

REMARKS

The Examiner is thanked for the courtesies extended during a telephonic interview conducted on September 3, 2003 with Stephen Brown of our firm. In the interview, the Examiner acknowledged that the compositions disclosed by Ribier require cubic gel particles. The Examiner indicated that the present claims would be allowable if amended to recite that the amount of dispersing agent is greater than the amount of phytantriol and if a Rule 132 declaration was submitted showing that cubic gel particles cannot be formed in a composition in which the amount of dispersing agent is greater than the amount of phytantriol. Accordingly, the claims have been amended herein as agreed, and a DECLARATION OF JÜRGEN VOLLHARDT, PH.D. UNDER 37 C.F.R. § 1.132 ("Declaration") is being filed concurrently herewith.

As requested by the Examiner, claims 1, 9, and 11 have been amended to recite that "the amount of dispersing agent is greater than the amount of phytantriol" and that the amount of phytantriol is "from about 01. to about 3% by weight." Support for these amendments is found in the specification at, for example, page 1, line 16 – page 3, line 2; page 5 lines 1-16; in Example 1; and in original claims 1, 9, 11. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Also, as agreed by the Examiner, claim 12 has been amended to recite that "the amount of dispersing agent is greater than the amount of phytantriol" and that the amount of phytantriol is "from about 01. to about 1% by weight." Moreover, claim 12 has been amended to correct an obvious typographical error. Support for these amendments is found in the specification at, for example, page 1, line 16 – page 3, line 2; page 5 lines 1-16; in Example 1; and in original claims 12. *Id.*

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

**Rejections Under 35 USC §§ 102 and 103 - Ribier Alone**

Claims 1, 3-6, and 12 were rejected under 35 USC §§ 102(b) and 103 as anticipated and/or obvious over Ribier *et al.*, US Patent No. 5,756,108 ("Ribier"). (Paper No. 11 at 2-5.)

For the reasons set forth below, the rejections, respectfully are traversed.

Ribier discloses:

a composition in the form of a dispersion comprising:

- (a) from 60 to 98% by weight of an aqueous phase, and
- (b) from 2 to 40% by weight of an oily phase, ***said oily phase being dispersed in said aqueous phase and stabilized by using cubic gel particles***, said particles being essentially formed of:
  - (i) 0.1 to 15% by weight, relative to the total weight of the composition, of at least one component selected from the group consisting of 3,7,11,15-tetramethyl-1,2,3-hexadecanetriol or phytanetriol, N-2-alkoxycarbonyl derivatives of N-methylglucamine and unsaturated fatty acid monoglycerides, and
  - (ii) 0.05 to 3% by weight, relative to the total weight of the composition, of a dispersing and stabilizing agent, said agent being selected from the group consisting of surface-active agents which are water-soluble at room temperature, containing a linear or branched, saturated or unsaturated fatty chain having from 8 to 22 carbon atoms. (Col. 1, line 56 - col. 2, line 7.)

Ribier discloses that "***it is possible to obtain dispersions*** of an oily phase in an aqueous phase, ***which are particularly stable and non-irritant, using a very large***

***variety of oils, by using cubic gel particles containing a low proportion of a water-soluble surface-active agent containing a fatty chain.***" (Col. 1, lines 33-40.)

Among the active principles that may be incorporated into the cubic gel particles, Ribier discloses natural dyes (Col. 6, lines 43-45) and hair dyes (Col. 7, lines 14-15.) To make the cubic gel particles, special process steps are disclosed including homogenizing a mixture of phytantriol, water and Polysorbate 40 with a high energy mixer to form a dispersion of the cubic gel particles. (See e.g., Example 1, Col. 9, lines 36-56.)

In making the rejection, the Examiner asserted that Ribier discloses "a cosmetic or dermatological composition containing an aqueous phase and an oily phase dispersed within." (Paper No. 11 at 2.) The Examiner noted that Ribier discloses that "although emulsions are easy to apply and impart good sensory properties, ***emulsions lack stability*** causing phase separation. Although this phase separation is prevented by the use of surfactants, excessive amounts of surfactants cause ***skin irritations***." (*Id.*) Accordingly, Ribier discloses "that the use of phytantriol ***cubic particles provides stability and less irritation*** since the cubic gel particles requires less surfactant." (*Id.*) The Examiner further asserted that "the composition contains 0.1-15% of a component such as phytantriol and 0.5-3% of a dispersing agent. Polysorbate 20 is taught as a dispersing agent." (*Id.*) The Examiner further asserted that Ribier discloses "natural dyes, oxidation couplers and bases (permanent dyes), direct dyes (semi-permanent dyes) and auto-oxidizable dyes." (*Id.*) Finally, the Examiner asserted that Ribier discloses "mixing the phytantriol in a dispersing agent

and an active ingredient....[and] the application of the composition on the area that is to be treated." (*Id.* at 2-3.)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984).

Initially, we note that claims 1 and 12 have been amended to recite that the amount of dispersing agent must be greater than the amount of phytantriol. As demonstrated in the Declaration, cubic gel particles of phytantriol can only be formed when the amount of phytantriol is greater than the amount of dispersing agent. (Declaration, ¶ 15.) Dr. Vollhardt, an expert in cosmetic formulation and chemistry, concludes that the formation of cubic gel particles of phytantriol is "impossible" when the amount of dispersing agent is greater than the amount of phytantriol as recited in the amended claims, and that Ribier, therefore, does not - and cannot - disclose compositions of cubic gel particles of phytantriol in which the amount of dispersing agent is greater than the amount of phytantriol. (*Id.*)

Cubic gel particles are the very heart of Ribier. Ribier explicitly discloses the shortcomings of previous compositions:

it is well known that **dispersions**, and in particular emulsions, **lack stability over time**, in particular on account of variations in temperature; these emulsions "break" giving rise to two separate phases, rendering them unusable.

The nature and the concentration of the emulsifying agent used may have a significant influence on the stability of such compositions.

However, it is well known that the choice and concentration of a suitable emulsifying agent will depend on various factors and, in particular, on the oil or oils constituting the oily phase of the dispersion or of the emulsion.

Moreover, it should be noted that certain surfactants are not free of drawbacks, in particular when they are employed at high concentration for the purpose of improving the stability.

Indeed, they may lead to certain *irritation phenomena* on sensitive skin. (Col. 1, lines 15-40.)

Ribier discloses that its cubic gel particle compositions overcome the stated shortcomings of certain prior art compositions:

It has now been observed, surprisingly and unexpectedly, that it is possible to obtain dispersions of an oily phase in an aqueous phase, which are particularly stable and non-irritant, using a very large variety of oils, *by using cubic gel particles containing a low proportion of a water-soluble surface-active agent* containing a fatty chain. The dispersions thus obtained moreover have particularly satisfactory sensory qualities.

Ribier discloses that the ratio of, e.g. phytantriol, to dispersing agent is between 2-200:1, preferably less than or equal to 50:1. (Col. 2, Ins. 12-16.) Moreover, every exemplified embodiment of the Ribier composition contains more phytantriol than dispersing agent as demonstrated in Table 1 below.

Example No.	Phytantriol (g)	Dispersing Agent (g)	Ratio of Phytantriol to Dispersing Agent
1	3.00	.95	3.15 : 1
2	2.97	.95	3.12 : 1
6	2.97	1.00	2.97 : 1
7	2.97	1.00	2.97 : 1
8	1.96	0.75	2.61 : 1
10	0.3	0.1	3 : 1

Table 1. Ratio of phytantriol to dispersing agent in Ribier examples.

In contrast, Examples 3-5 were prepared as comparative examples and did not form cubic gel particles. (Col. 10, ln. 58 - Col. 11, ln. 9.) These compositions were compared to Examples 1 and 2. Based on this comparison, Ribier concludes “[t]he result of this comparative study is that **only the presence of cubic gel particles leads to dispersions having good stability.**” (Col. 11, lines 6-8.)

Accordingly, Ribier discloses and only exemplifies compositions wherein the amount of phytantriol is greater than the amount of dispersing agent, in order to form cubic gel particles of phytantriol. And, as shown by Dr. Vollhardt, cubic gel particles cannot be formed unless conditions exemplified in Ribier are used, namely a ratio of e.g., phytantriol:dispersing agent of greater than 1:1 and mixing with a high intensity mixer. (See e.g., Declaration, ¶¶9-15.) Claims 1 and 12, as amended, recite that the amount of dispersing agent must be greater than the amount of phytantriol. Thus, each and every element of the claimed invention is not disclosed by Ribier. For this reason, it is respectfully submitted that the §102 rejection must be withdrawn.

With respect to the §103 rejection based on Ribier alone (Paper No. 11, pp. 3-5), we note that obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness **must** be based upon facts, “cold hard facts.” *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993).

As discussed above with respect to the §102 rejection, the Examiner apparently assumes that the Ribier compositions are not limited to cubic gel particles or that the presently claimed invention embraces cubic gel particles. Dr. Vollhardt,

however, concludes that the compositions utilized in the present claims do **not** form cubic gel particles and that the Ribier compositions are limited to cubic gel particles based on the ratio of e.g. phytantriol:dispersing agent used and the requirement of a high intensity mixer. (See e.g., Declaration, ¶¶9-15.) Thus, the rejection relies on a factually deficient interpretation of Ribier. Because the rejection is factually incorrect, it cannot stand. For this reason alone, we respectfully request withdrawal of the rejection.

We also note that it is well settled that to modify a reference to do what it explicitly teaches against is the antithesis of obviousness. *In re Buehler*, 185 USPQ 781, 789 (CCPA 1975) ("Appellant's claimed method, however, involves doing what Clark [the asserted prior art reference] tries to avoid, .... This is the very antithesis of obviousness.") and *In re Rosenberger*, 156 USPQ 24, 26 (CCPA 1967) ("They have invented a method for producing an effective protective coating in the face of art which strongly suggests that such a method would produce unacceptable results. This is the very antithesis of obviousness.")

As noted by Dr. Vollhardt, the presently claimed invention utilizes micellar compositions, which do **not** form cubic gel particles. (See e.g., Declaration, ¶¶14-15 and Fig. 3.) Dr. Vollhardt's conclusion is further reflected in the amended claims, which recite that the amount of dispersing agent is greater than the amount of phytantriol. Thus, the claims specifically exclude cubic gel particles, which Dr. Vollhardt testifies cannot be formed unless a high energy mixer is used and the amount of polar lipid (e.g., phytantriol) is greater than the amount of dispersing agent. (See Declaration, ¶15.)

Thus, to support the rejection, the Examiner requires one to modify Ribier so that non-cubic gel particles are utilized. The Examiner, however, has identified no reason or suggestion why one skilled in the art would modify Ribier - which the Examiner admits requires cubic gel particles - to prevent the formation of cubic gel particles by modifying the compositions to contain more dispersing agent compared to, e.g., phytantriol. Nor does the Examiner identify any reason to ignore the clear teaching of Ribier that the use of cubic gel particles in, e.g., cosmetic formulations, remedies certain stated infirmities of prior art dispersions, namely lack of stability and skin irritation. (See e.g., Col. 1, Ins. 33-40.)

Without any evidence to suggest modifying Ribier to obtain non-cubic gel dispersions of the type utilized by the claims, there is no motivation or suggestion to do as the Examiner proposes. For this reason also, it is respectfully submitted that the rejection falls short of a *prima facie* case and must be withdrawn.

#### **Rejections under 35 USC § 103 - Ribier In Combination**

Claims 2 and 6-7 were also rejected under 35 USC § 103(a) as being unpatentable over Ribier in view of Saphakkul, U.S. Patent No. 4,964,874 ("Saphakkul"). (Paper No. 11 at 6.)

For the reasons set forth below the rejection, respectfully is traversed.

Ribier is summarized above.

Saphakkul discloses a product for conditioning and dying hair in order to darken it. (Col. 1, Ins. 6-7.) The hair conditioning product includes an aqueous medium a cationic surfactant and a fatty alcohol, wherein the surfactant is present in the form a

disperse lamellar liquid crystal phase. (Col. 2, Ins. 25-27.) The hair conditioner product may contain one or more basic dyes, such as, anthraquinone dyes. (Col. 2, ln. 66 - Col. 3, ln. 2.)

In making the rejection, the Examiner relied on Ribier in the same manner as in the §§ 102 and 103 rejections discussed above. (Paper No. 11 at 5.) The Examiner acknowledged, however, that Ribier does not disclose "the type of direct dye that can be used or the amount." (*Id.*)

To fill this acknowledged gap, the Examiner relied on Saphakkul as disclosing the use of direct dyes, such as anthraquinones, for coloring hair. (*Id.*) The Examiner then concluded that it would have been obvious add the direct dyes of Saphakkul to the dispersions of Ribier containing cubic gel particles. (*Id.*, p. 5.)

As noted above, Ribier - the primary reference - requires cubic gel particles. Also as discussed above, all of the claims that are pending and under examination, including claims 2, 6 and 7, as amended, recite that "the amount of dispersing agent is greater than the amount of phytantriol." And, as Dr. Vollhardt testifies, it is impossible to form a cubic gel particle from a composition wherein the amount of dispersing agent is greater than the amount of phytantriol. (Declaration, ¶15.)

Accordingly, Ribier alone does not disclose or suggest the presently claimed method because cubic gel particles are required by Ribier and are expressly excluded from the present claims. And, the rejection does not explain how this factual gap in Ribier is remedied by Saphakkul. Accordingly, it is respectfully submitted that the rejection cannot stand and must be withdrawn.

Claims 9-11 were also rejected under 35 USC § 103(a) as being unpatentable over Ribier in view of Wenke *et al.*, U.S. Patent No. 5,628,799 ("Wenke"). (Paper No. 11 at 6.)

For the reasons set forth below the rejection, respectfully is traversed.

Ribier is summarized above.

Wenke discloses a process for dying hair using dopa (dihydroxyphenylalanine) and/or substituted dopa compounds to generate melanin pigments for use as a permanent hair dye. (Col. 1, lines 16-19.) Wenke discloses that "the color obtained by oxidation of the dopa species can be significantly modified by including direct dyes and, if desired, primary intermediates, and/or couplers in the reaction medium." (Col. 4, line 66 - Col. 5, line 2.) Wenke also discloses hair dying kit products, wherein the kit includes "a first container containing a dopa species solution containing the direct dye or, optionally the primary intermediate and/or coupler, and a second container containing the oxidant solution." (Col. 12, lines 12-17.)

In making the rejection, the Examiner relied on Ribier in the same manner as in the §§ 102 and 103 rejections discussed above. (Paper No. 11 at 6.) The Examiner acknowledged, however, that Ribier does not disclose "a specific hair dye kit where the primary reactor (oxidizing agent) and secondary reactor (coupler) are in separate packs." (*Id.*) To fill this acknowledged gap, the Examiner relied on Wenke as disclosing "a hair dye kit in which the oxidizing agent and a coupler are pre-measured in different containers and mixed together by the user." (*Id.*)

The Examiner concluded that:

[i]t would have been obvious ... to combine [Ribier and Wenke] and provide a hair dye kit. One would be motivated

to do so [because] Wenke et al teach the advantages of using a kit to provide permanent hair color such as correct use by the consumer and in-home use. Furthermore, one would expect similar results since Ribier et al teach utilizing permanent dyes with an oxidizing and coupling agent. Lastly, one would be motivated to use the permanent hair dye of Wenke since Wenke teaches that the hair dyes provides [sic] color durability during repeated shampoos. (*Id.* at 6-7.)

As noted above, Ribier discloses compositions containing cubic gel particles made from, e.g. phytantriol. As Dr. Vollhardt testifies, it is impossible to form cubic gel particles when the amount of dispersing agent is greater than the amount of e.g. phytantriol and a conventional (*i.e.*, not high intensity) mixer is used. (Declaration, ¶15.) And, as noted above, the Examiner has provided no evidence why one would ignore the express teachings of Ribier to form cubic gel particles and instead form the type of micellar compositions as used in the claims. The Examiner also does not identify any disclosure in Wenke that would remedy this gap. Thus, even if Wenke is properly combinable with Ribier, which is not admitted, the proposed combination would still fall short of a *prima facie* case. Accordingly, it is respectfully submitted that the rejection should be withdrawn for this reason alone.

We also note that the Examiner has the burden of establishing (1) that there is suggestion or motivation to combine the references relied upon, and (2) that the references, when so combined, contain the requisite suggestion and motivation which would have led one to combine the particular disclosure relied upon and to make a composition as claimed. *In re Dembiczaik*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Here, the Examiner has provided no evidence to suggest that the specific dopa species disclosed by Wenke would work in the compositions containing cubic gel

particles disclosed by Ribier. No evidence or technical reasoning is provided that would suggest that the Wenke dopa species would survive and be functional following the formation of the cubic gel particles with the special high intensity mixer used. (See e.g. Examples and Col. 8, Ins. 37-40.) Thus, the rejection does not contain the requisite evidence with respect to suggestion and motivation in Ribier and Wenke to combine these documents in the manner set forth in the Office Action. For this reason as well, it is respectfully submitted that the rejection is deficient and should be withdrawn.

Claim 11 was also rejected under 35 USC § 103(a) as being unpatentable over Ribier in view of Savaides *et al.*, U.S. Patent No. 5,350,572 ("Savaides") and Krutak *et al.*, U.S. Patent No. 5,951,718 ("Krutak"). (Paper No. 11 at 8.)

For the reasons set forth below the rejection, respectfully is traversed.

Ribier is summarized above.

Savaides discloses compositions and processes for "permanently waving hair ... to provide substantially increased, long-lasting, durable, permanently waved hair while also substantially reducing the malodor typically associated with permanent waving." (Col. 1, lines 5-11.)

Krutak discloses compositions and processes for non-permanently coloring keratinous fibers using sulfo-containing, water-dispersible, "colored polymers wherein the colorant moiety is incorporated into or onto a carboxyloxy and/or carbonylamide backbone of the polymer." (Col. 1, lines 14-16.) Krutak discloses that "[t]he polymers are uniquely designed to offer cosmetically desirable color coating on hair and to be easily dispersible in hot water, yet offer excellent resistance to redispersion in water at room temperature." (*Id.* at lines 16-21.)

In making the rejection, the Examiner relied on Ribier in the same manner as in the §§ 102 and 103 rejections based on Ribier alone. (Paper No. 11 at 8.) The Examiner acknowledged, however, that Ribier does not disclose "color durability of the compositions." (*Id.*) To fill this acknowledged gap, the Examiner relied on Savaides as disclosing "permanent waving compositions [wherein] ... phytantriol is a penetrating agent." (*Id.*) Moreover, the Examiner relied on Krutak as disclosing coloring hair "using low molecular weight compounds, which penetrate the keratinous fiber. [Krutak] states that it becomes very difficult even after repeated shampoo to remove color that has penetrated the hair fibers." (*Id.*)

The Examiner concluded that:

[i]t would have been obvious ... to look to [Savaides and Krutak] and utilize Ribier's composition to increase color durability. One would be motivated to do so since Savaides teaches that phytantriol is a penetration enhancer and Krutak teaches that when the color molecule penetrates the hair it cannot be washed out of the hair easily; therefore with the teaching of the prior art a skill[ed] artisan would ascertain that Ribier's composition would implicitly increase color durability since phytantriol is known as a penetration enhancing agent. (*Id.* at 9.)

As noted above, Ribier - the primary reference - requires cubic gel particles. Also as discussed above, all of the claims that are pending and under examination, including claim 11, as amended, recite that "the amount of dispersing agent is greater than the amount of phytantriol." And, as Dr. Vollhardt testifies, it is impossible to form a cubic gel particle from a composition wherein the amount of dispersing agent is greater than the amount of phytantriol. (Declaration, ¶15.)

Accordingly, Ribier alone does not disclose or suggest the presently claimed method because cubic gel particles are required by Ribier and are expressly

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excluded from the present claims. And, the rejection does not explain how this factual gap in Ribier is remedied by Savaides and Krutak. Accordingly, it is respectfully submitted that the rejection cannot stand and must be withdrawn.

For the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 29, 2003.

  
Kevin C. Hooper, Reg. No. 40,402

Respectfully submitted,

By:  Reg. No. 40,402 for  
Stephen J. Brown  
Registration No. 43,519  
BRYAN CAVE LLP  
1290 Avenue of the Americas  
33<sup>rd</sup> Floor  
New York, NY 10104-3300  
Phone: (212) 541-2000  
Fax: (212) 541-4630